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10/720,992	11/25/2003	Paul Jackson	37965-0021	3359
7590	01/22/2008		EXAMINER	
John P. Isacson Heller Ehrman White & McAuliffe 815 Connecticut Avenue, NW Suite 200 Washington, DC 20006			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			01/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

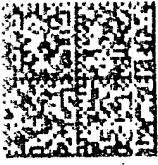
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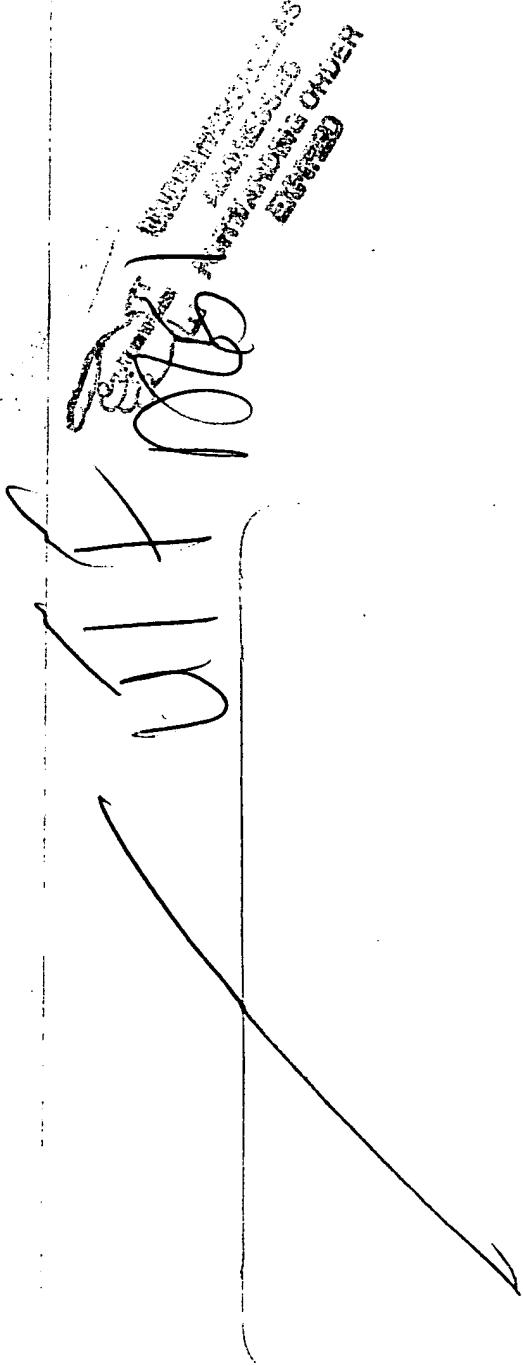
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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/720,992	JACKSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Shengjun Wang	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-30 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to products not embraced by the products of Groups II-XIV defined below.
- II. Claims 4 and 5, drawn to products of core structure (I) wherein X and X<sub>1</sub> are each CR2R3, classified in class 548, subclass 530+.
- III. Claims 4 and 5, drawn to products of core structure (I) wherein X is CR2R3 and X<sub>1</sub> is O or X is O and X<sub>1</sub> is CR2R3, classified in class 548, subclass 215 +.
- IV. Claims 4 and 5, drawn to products of core structure (I) wherein X is CR2R3 and X<sub>1</sub> is S or X is S and X<sub>1</sub> is CR2R3, classified in class 548, subclass 146+.
- V. Claims 4 and 5, drawn to products of core structure (I) wherein X is CR2R3 and X<sub>1</sub> is N or X is N and X<sub>1</sub> is CR2R3, classified in class 548, subclass 300.1 +.
- VI. Claims 6 and 7, drawn to products of core structure (II) wherein X is CR2R3, classified in class 546, subclass 184+.
- VII. Claims 6 and 7, drawn to products of core structure (II) wherein X is O, classified in class 544, subclass 106+.

VIII. Claims 6 and 7, drawn to products of core structure (II)

wherein X is S, classified in class 544, subclass 3+.

IX. Claims 6 and 7, drawn to products of core structure (II)

wherein X is NR4, classified in class 544, subclass 336+.

X. Claims 8 and 9, drawn to products of core structure (III),

classified in classes 562,564, etc.

XI. Claims 10 and 11, drawn to products of core structure (IV)

wherein X is CR2R3 and X<sub>1</sub> is CR2R3, classified in class 562.

XII. Claims 10 and 11, drawn to products of core structure (IV)

wherein X is CR2R3 and X<sub>1</sub> is O or X is O and X<sub>1</sub> is CR2R3,

classified in class 549, subclass 429+.

XIII. Claims 10 and 11, drawn to products of core structure (IV)

wherein X is CR2R3 and X<sub>1</sub> is S or X is S and X<sub>1</sub> is CR2R3,

classified in class 549, subclass 29+.

XIV. Claims 10 and 11, drawn to products of core structure (IV)

wherein X is CR2R3 and X<sub>1</sub> is NR4 or X is NR4 and X<sub>1</sub> is

CR2R3, classified in class 548, subclass 530+.

XV. Claims 12-14 and 21-28, drawn to methods of using products

of core structure (I) wherein X and X<sub>1</sub> are each CR2R3,

classified in class 514, subclass 408+.

XVI. Claims 12-14 and 21-28, drawn to methods of using products

of core structure (I) wherein X is CR2R3 and X<sub>1</sub> is O or X is

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O and X<sub>1</sub> is CR2R3, classified in class 514, subclass 374+.

XVII. Claims 12-14 and 21-28, drawn to methods of using  
products of core structure (I) wherein X is CR2R3 and X<sub>1</sub> is S  
or X is S and X<sub>1</sub> is CR2R3, classified in class 514, subclass 365+.

XVIII. Claims 12-14 and 21-28, drawn to methods of using  
products of core structure (I) wherein X is CR2R3 and X<sub>1</sub> is N  
or X is N and X<sub>1</sub> is CR2R3, classified in class 514, subclass 396+.

XIX. Claims 15, 16 and 21-28, drawn to methods of using  
products of core structure (II) wherein X is CR2R3, classified  
in class 514, subclass 315 +.

XX. Claims 15, 16 and 21-28, drawn to methods of using  
products of core structure (II) wherein X is O, classified in  
class 514, subclass 231.2 +.

XXI. Claims 15, 16 and 21-28, drawn to methods of using  
products of core structure (II) wherein X is S, classified in  
class 514, subclass 227.5+.

XXII. Claims 15, 16 and 21-28, drawn to methods of using  
products of core structure (II) wherein X is NR4, classified in  
class 514, subclass 252.1 +.

XXIII. Claims 17, 18 and 21-28, drawn to methods of using  
products of core structure (III), classified in class 514,  
subclass 613 +.

XXIV. Claims 19-28, drawn to methods of using products of core structure (IV) wherein X is CR<sub>2</sub>R<sub>3</sub> and X<sub>1</sub> is CR<sub>2</sub>R<sub>3</sub>, classified in class 514, subclass 553+.

XXV. Claims 19-28, drawn to methods of using products of core structure (IV) wherein X is CR<sub>2</sub>R<sub>3</sub> and X<sub>1</sub> is O or X is O and X<sub>1</sub> is CR<sub>2</sub>R<sub>3</sub>, classified in class 514, subclass 461 +.

XXVI. Claims 19-28, drawn to methods of using products of core structure (IV) wherein X is CR<sub>2</sub>R<sub>3</sub> and X<sub>1</sub> is S or X is S and X<sub>1</sub> is CR<sub>2</sub>R<sub>3</sub>, classified in class 514, subclass 438+.

XXVII. Claims 19-28, drawn to methods of using products of core structure (IV) wherein X is CR<sub>2</sub>R<sub>3</sub> and X<sub>1</sub> is NR<sub>4</sub> or X is NR<sub>4</sub> and X<sub>1</sub> is CR<sub>2</sub>R<sub>3</sub>, classified in class 514, subclass 423 +.

XXVIII. Claims 21, 22 and 24-27, drawn to methods of using an inhibitor of dipeptidyl peptidase IV not embraced by Groups XV-XXVII, classified in class 514.

XXIX. Claim 29, drawn to methods of using products, classified in class 514, subclass 365 +.

XXX. Claim 30, drawn to methods of using products, classified in class 514, subclass 408+.

2. Inventions groups I-XIV and XV-XXX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product, such as the product of group II, or III.

3. Inventions groups I-XIV or groups XV-XXX are unrelated each from the others.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation. Particularly, the several inventions above are independent and distinct, each from the other, as they are directed to structurally distinct compounds (or method of using them), as evidenced by the different class/subclass, and have acquired a separate status in the art of treating as a separate subject matter for inventive effect and require independent searches. It is noted that a reference to one group of compounds would not be a reference to another group of compound under 35 U.S.C. 103. Further, the claims read on a multitude of compounds, and a variety of disorders, which would require many field of searches that would be an undue burden on the Examiner.

Therefore, restriction for examination purposes is proper.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claims 1-30 are generic to the following disclosed patentably distinct species: a variety of compounds. The species are independent or distinct because of the structure distinct features. It is noted that each group of compounds has plural substituents and each substituent represent a

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group of distinct moiety. For examples, in formula (I), A may be H, COOH, CN, SO<sub>3</sub>H, etc.. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The inventions of Groups I and XXVIII do not specify a particular product in the claims which fall under these groups. If either of these groups is elected, a generic concept, which would embrace the elected species, will be identified by the Examiner for examination.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

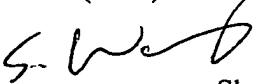
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Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
CHENGJUN WANG  
PRIMARY EXAMINER

Shengjun Wang  
Primary Examiner  
Art Unit 1617